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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/636,182	08/07/2003	Christopher A. Thierfelder	AMS-161	1760

7590 04/27/2007

Attention: Jeffrey J. Hohenshell
AMS Research Corporation
10700 Bren Road West
Minnetonka, MN 55343

EXAMINER
GILBERT, ANDREW M

ART UNIT	PAPER NUMBER
3767	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/636,182	THIERFELDER ET AL.	
	Examiner	Art Unit	
	Andrew M. Gilbert	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/12/2007 has been entered.

Acknowledgements

1. This office action is in response to the reply filed on 2/12/2007 and 11/20/2006.

2. In the reply, the Applicant amended claims 13 and 16.

3. Thus, claims 13-16 remain pending for examination.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 13, 15, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Heil, Jr. (5041107). Heil, Jr. discloses an implantable drug delivery system (10) having a storage area (14; col 5, lns 29-38) for storing a drug; a metering for metering a predetermined, effective amount of the drug though a drive electrode (22), a power source (12) and oppositely charged return electrode (26) (col 2, lns 8-56; col 4, lns 16-

30); a delivery means for delivering an effective amount of drug comprising a catheter (14) having a longitudinal axis (Fig 1) and having a plurality of drug delivery ports (22, 32, 44) being a plurality of slits (22, 32, 44) that are movable between an open position to delivery the drug to the patient and a closed position (col 3, lns 54-56; col 4, lns 7-9; col 4, lns 16-30); a drug delivery path preservation means comprising a substance for resisting the fibrous occlusion proximate and in the drug delivery ports and wherein the substance is in the drug delivery ports (col 4, lns 36-46, col 4, lns 58-63; wherein the Examiner notes that the portion of the catheter body (36, 38) whereby the film or membrane (34) is tightly conformed over and attached is proximate and structured over the drug delivery port and the film or membrane (34) is a substance that resists formation of fibrous occlusions, such as blood clots via fibrinogen and thrombin (col 6, lns 40-43, lns 58-63). Also see discussion below in response to arguments.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heil, Jr. in view of Urry (5520672). Heil, Jr. discloses the invention substantially as claimed except for disclosing that the substance for resisting fibrous occlusions comprises poly(glycine-valine-glycine-valine-proline) or poly(GVGVP). Urry teaches that it is known to have substance for resisting fibrous occlusions comprises poly(glycine-valine-glycine-

valine-proline) or poly(GVGVP) (col 7, lns 67-col 8, lns 5) for the purpose of preventing fibrous encapsulation to occur when implanted in a living system (col 7, lns 67-col 8, lns 5). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the substance as taught by Heil, Jr. with the poly(GVGVP) as taught by Urry for the purpose of preventing fibrous encapsulation to occur when implanted in a living system (col 7, lns 67-col 8, lns 5).

Response to Arguments

8. Applicant's arguments filed 11/20/2006 have been fully considered but they are not persuasive.

9. The Applicant argues that:

i. Heil only discloses preventing occlusion of the drug deliver slits by a physical barrier (Remarks, pg 5, paragraph 4).

ii. Heil does not teach the delivery of a substance to the drug delivery ports that resists fibrous occlusion (Remarks, pg 5, paragraph 4).

iii. Heil fails to supply any logic why would should replace a physical barrier with a substance (Remarks, pg 5, paragraph 4) and Urry fails to supply any reason to replace the physical barrier with such a substance or disclose the use of such materials as a drug delivery catheter with a plurality of drug ports thus there is no motivation to combine the references of Heil and Urry (Remarks, pg 6, paragraph 1-2).

10. In response to applicant's argument (i) the Examiner notes that Heil does not *only* disclose preventing occlusion of the drug delivery slits by a physical barrier.

Rather, in addition to the slits (22, 32, 44) Heil discloses a plastic membrane (34) bonded to the catheter body at (36) and (38) in tightly conformed and covering relation to the slits (22, 32, 44). The material of the membrane is selected so as to have a desired molecular weight cut-off property and more specifically to be a total barrier against the high molecular weight blood clot forming substances such as fibrinogen and thrombin (col 4, lns 38-43, 58-63). This allows the slot to remain patent over long period of implantation within the body (col 4, lns 44-45). Additionally, the membrane is also closed to create a *barrier to the outflow* of the delivery drug (col 4, lns 46-48). This means that the membrane is also explicitly disclosed as being part of the drug delivery port, thus, the substance for resisting fibrous occlusions is in the drug delivery ports. Heil additionally discloses that the membrane may be comprised of various biocompatible plastics (col 4, lns 60-63).

11. In response to applicant's argument (ii) that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the delivery of a substance to the drug delivery ports that resists fibrous occlusion) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In the instant case, the Applicant has merely recited that a substance is provided in the drug delivery ports that resists fibrous occlusion. There is no recitation of delivery of such a substance in the claims. Thus, Heil reads on the claims because Heil discloses a substance (34) is provided in the drug delivery ports that resists fibrous occlusion (col 4, lns 37-63).

12. In response to applicant's argument (iii) that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the Examiner notes the Heil discloses both a barrier and a substance as delivery means and delivery path preservation means (see above discussion to argument (i). Heil additionally discloses that the membrane may be comprised of various biocompatible plastics (col 4, lns 60-63). The important characteristics of the material chosen for Heil's membrane (36) are its ability to be a barrier against blood clot forming substances such as fibrogen and thrombin so the catheter's lumen remains free of occlusion and in a working state over prolonged periods of implantation in the body. The Examiner notes that Urry discloses biocompatible substances for resisting fibrous occlusions on implanted devicers. Specifically, Urry discloses that poly(VPGVG) is a very biocompatible material that shows no tendencies to cause formation of protein coatings and fibrous encapsulation when implanted in living systems (col 7. lns 67-col 8, lns 5). Thus, the Examiner finds that there is proper motivation to combine the teachings of Urry involving the biocompatible poly(VPGVP)'s ability to resist fibrous encapsulation on implantation as a biocompatible material in the membrane of Heil that desires resisting of fibrous encapsulation on implantation. The rejection is maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andrew Gilbert

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER